

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 25 OCT 2004

WIP **PCT** PCT

To:

see form PCT/SA/220

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/SA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/SA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/009838

International filing date (day/month/year)
31.03.2004

Priority date (day/month/year)
31.03.2003

International Patent Classification (IPC) or both national classification and IPC
A61K31/715, A61K38/00, A61K35/74, A61P37/00

Applicant
THE BRIGHAM AND WOMEN'S HOSPITAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/SA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/SA/220.

3. For further details, see notes to Form PCT/SA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/009838

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/009838

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/009838

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-71

because:

☒ the said international application, or the said claims Nos. 1-71 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/009838

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-22,24-56,58,59,63-97
	No: Claims	1,23,57,60-62
Inventive step (IS)	Yes: Claims	2-22,24-56,58,59,63-97
	No: Claims	1,23,57,60-62
Industrial applicability (IA)	Yes: Claims	72-97
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

SECTION III

Claims 1-71 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

SECTION V

1. The following documents are referred to in the present opinion. If not otherwise specified reference is made to the relevant passages cited in the International Search Report.

D1: WO 03/075953 A

D2: EP-A-1 459 757

D3: TZIANABOS A O ET AL: "T cells activated by zwitterionic molecules prevent abscesses induced by pathogenic bacteria" JOURNAL OF BIOLOGICAL CHEMISTRY, AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BALTIMORE, MD, US, vol. 275, no. 10, 10 March 2000 (2000-03-10), pages 6733-6740

D4: KALKA-MOLL W M ET AL: "Effect of molecular size on the ability of zwitterionic polysaccharides to stimulate cellular immunity" JOURNAL OF IMMUNOLOGY, THE WILLIAMS AND WILKINS CO. BALTIMORE, US, vol. 164, no. 2, 15 January 2000 (2000-01-15), pages 719-724

D5: EP-A-1 358 885

D6: US-A-4 835 252

D7: PATENT ABSTRACTS OF JAPAN vol. 0060, no. 03 (C-086), 9 January 1982 (1982-01-09) & JP 56 128721 A (EISAI CO LTD), 8 October 1981 (1981-10-08)

D3 deals with the action of zwitterionic molecules in the prevention of abscesses induced by pathogenic bacteria. It describes also the activation of T cells by natural and synthetic zwitterionic molecules.

D4 describes the ability of zwitterionic polysaccharides to activate T cells in correlation with their molecular size.

D6 deals with vasoactive intestinal peptide analogs. It also describes the use of VIP

in asthmatic bronchospasm.

D7 deals with peptidic composition in the treatment of allergies, including VIP peptides.

Claims 1,19,23,37,46,57,60,67,73 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims give a vague definition of the parameters necessary to differentiate the claimed subject-matter over the prior art.

2. Furthermore, the above-mentioned lack of clarity notwithstanding, in view of the cited prior art the subject-matter of claims 1, 23,57,60-62 is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met. In particular, D3 and D4 seem to anticipate the subject-matter of claims 57, 60-62, D7 seem to anticipate claim 1 and 23.
3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1,23,57,60-62 does not involve an inventive step in the sense of Article 33(3) PCT. The problem to be solved by the present application may be summarized as how to provide an alternative zwitterionic polymer in the treatment of allergic conditions. The solution proposed in the present application is to provide a polymer having a positively charged free amino moiety and a negatively charged moiety selected from the group of carboxyl, phosphate, phosphonate, sulfate and sulfonate. However said solution seems to have been provided by the cited prior art.
4. Claim 13,25,31,45,56,64,82 contain a references to the description. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.
5. For the assessment of the present claims 1-71 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

SECTION VI

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/009838

Certain documents cited

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO03075953	18.09.03	07.03.03	08.03.02
EP1459757	22.09.04	31.03.00	02.04.99